

standard treatment for this age group. Several recent studies suggest superiority of combination CT, but little is known about QoL during CT. Also better assessments are needed to select elderly pts suitable for combination CT. The aim of this study was to investigate the effect of both platinum-based regimens on changes in QoL and the tolerability of these treatments in elderly NSCLC pts.

Methods: Eligible were pts ≥ 70 years with advanced NSCLC. They received carboplatin (AUC 5 day 1)-gemcitabine (1250 mg/m² days 1 and 8) or carboplatin (AUC 5 day 1)-paclitaxel (175 mg/m² day 1), q 3 weeks, for a maximum of 4 cycles. Darbepoetin was started if Hb < 11 g/dL. Primary endpoint was the change in global QoL from baseline compared with week 18, using the EORTC QLQ-C30. Among the secondary endpoints were toxicity, response rate and survival. In addition, the value of a comprehensive geriatric assessment (CGA) was used.

Results: 182 pts were randomized. At the time of this analysis information was available on 168 pts. Mean age was 75 yrs (range 70-85). PS = 0 in 30%, 1 in 57% and 2 in 13%. 64% of pts completed all 4 cycles, 10% stopped treatment prematurely due to toxicity, 13% due to PD. Toxicity related dose-reductions occurred in 28 and 8% of pts and dose-delays in 15 and 3% of pts in the CG and CP arm, respectively. Overall, grade III/IV toxicity occurred in 65% of pts (75% in CG arm, 56% in CP arm), toxicity related SAEs in 17% (20% in CG arm, 15% in CP arm), and 36% experienced \geq grade 2 neurological toxicity (30% CG arm, 43% CP arm). Response rates were 28% in the CG arm vs 20% in the CP arm. Median survival and progression-free survival were 7.7 and 4.7 months for the CG arm and 6.6 and 4.4 months for the CP arm, respectively. 56 % of pts in the CG arm and 49% in the CP arm completed both the QoL questionnaires at baseline and after 18 weeks. Mean global QoL score at baseline did not differ between both arms (66% for GC and CP). After 18 weeks the mean QoL score for the CG arm had decreased by 2% and for the CP arm by 8% (NS). Furthermore, changes in QoL scores over the period of 18 weeks did not differ significantly between both treatment arms. For experiencing grade III/IV toxicity related SAEs, neurological toxicities and for finishing all cycles, the use of a CGA was of predictive value.

Conclusions: In elderly patients with advanced NSCLC differences in treatment-related toxicity from gemcitabine and paclitaxel administered with carboplatin have no differential influence on QoL. Response and survival rates are similar for both groups.

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NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4

Weekly docetaxel-cisplatin as first-line treatment for advanced non-small cell lung cancer (NSCLC): results of a multicenter phase II trial

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Background: The combination of docetaxel and cisplatin is an effective first-line chemotherapy for advanced NSCLC. However, the recommended three-weekly schedule is frequently associated with neutropenia and neutropenic infections. Moreover, the relatively long

hydration required with cisplatin given every three weeks makes outpatient treatment more difficult. We assessed the efficacy and tolerability of weekly docetaxel-cisplatin, which may be better tolerated than the standard regimen.

Methods: Patients (pts) with histologically confirmed stage UICC IIIB (malignant effusion) or IV NSCLC received docetaxel (35 mg/m², 30 min. infusion) and cisplatin (25 mg/m², 30-min. infusion) on days 1, 8, and 15, every 4 weeks for 4-6 cycles. Pts received ondansetron 8 mg iv and dexamethasone 8 mg iv preceding every day of chemotherapy and oral dexamethasone 2 x 4 mg daily from the day before until the day after chemotherapy. NK1-antagonists were given at the investigator's discretion. Most pts were treated in an outpatient department. Safety was assessed using CTCAE v3.0. The primary endpoint was response rate (RECIST).

Results: 45 pts were included; efficacy and tolerability data were available for 43 pts. 12/45 pts achieved an objective response (11 partial; 1 complete; ITT response rate 27%). Median time to progression was 3.9 months. Pts received a median of 3 full cycles. 4 pts (9%) required dose reductions. No cases of neutropenic fever/infections or grade 2-4 thrombocytopenia were observed. One pt (2%) experienced grade 3/4 nausea/vomiting. 5 pts died during therapy for reasons not unequivocally attributable to tumor progression (bacterial meningitis with normal neutrophil counts [n=1], pneumonia with normal neutrophil counts [n=1], pulmonary arterial embolism [n=1], unknown [n=2]).

Conclusions: Weekly docetaxel-cisplatin was well tolerated. The schedule can be safely administered with relatively low hydration volumes in an outpatient setting. Survival data will be presented.

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A retrospective study of the role of chemotherapy in non-small cell lung cancer (nscl) patients with brain metastases treated in Alberta, Canada from 2000-2004

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Metastatic NSCLC clinical trials evaluating the role of palliative chemotherapy often underrepresent or exclude patients with brain metastases. The prognosis for this subgroup of patients remains poor and the advantage of chemotherapy, after definitive whole brain radiotherapy (WBRT), remains unclear. A retrospective chart review of NSCLC patients presenting with synchronous brain metastases in Alberta, Canada from 2000-2004 was undertaken to examine the possible benefits of chemotherapy following WBRT. 497 chemonaïve NSCLC patients with brain metastases received brain radiotherapy from 2000-2004, but only 30 patients (6%) received subsequent chemotherapy. Of the 30 patients, the median age was 54 years (range 29 to 69 years), 40% were male, 87% had an ECOG performance status ≤ 2 and 60% had adenocarcinoma subtype of NSCLC. The treatment of the brain metastases, prior to chemotherapy, consisted primarily of WBRT (62% of patients irradiated with 30 Gy in 10 fractions; 38% patients irradiated with 20 Gy in 5 fractions), whereas only one patient underwent stereotactic radiosurgery. An intracranial response or stable disease was observed in 66% of patients. When treated with chemotherapy after brain radiotherapy, 97% received a platinum-based doublet for a median of 4 cycles (range 1-6). The response rate to first-line chemotherapy was 30%, and 10